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**TITLE:** Post Admission Cognitive Therapy (PACT) for the Inpatient Treatment of Military Personnel with Suicidal Behaviors: A Multi-Site Randomized Controlled Trial

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**CONTRACTING ORGANIZATION:**

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## Introduction

**Background:** Suicide remains a serious national public health problem and has become a leading cause of death in the United States military. To date, there is no evidence-based civilian or military inpatient interventions aimed at the reduction of suicide behavior. Our proposal addresses this important gap and aims to evaluate an innovative suicide intervention, *Post Admission Cognitive Therapy* (PACT). Left untreated, severe suicide ideation and/or suicide attempts that require psychiatric hospitalization may place an individual at a lifetime risk for increased psychopathology, subsequent suicide behavior, and death.

**Objective:** The broad objective of the proposed study is to empirically evaluate the efficacy of a cognitive behavioral intervention, titled, *Post Admission Cognitive Therapy* (PACT), for military service members psychiatrically admitted for inpatient care due to a suicide-related event with either a recent or a lifetime suicide attempt.

**Specific Aims:** To evaluate the efficacy of PACT plus Enhanced Usual Care (EUC) versus EUC for the prevention of suicide in psychiatrically hospitalized military personnel at follow-up (1, 3, 6, and 12-month) on (1) incidence of repeat suicide attempt(s) and number of days until a repeat suicide attempt (primary outcomes), and (2) psychiatric symptoms (depression, trauma, sleep, suicide ideation), repeat number of psychiatric hospitalization(s), hope for one's future, and acceptability of treatment (as measured by time to linkage to specialty care, attitudes toward seeking help for mental health issues, and subsequent mental health service utilization) (secondary outcomes). We expect that adults in the PACT+EUC (experimental) condition compared to those in the EUC (control) condition will show favorable outcomes on both primary and secondary measures.

**Study Design:** The research design is a multi-site, single-blind, randomized controlled trial (RCT). A total of 218 individuals who are over the age of 18, able to communicate in English and willing to provide informed consent will be recruited from the inpatient psychiatric units at Walter Reed National Military Medical Center (WRNMMC) and Fort Belvoir Community Hospital (FBCH). Participants will be randomized into one of two conditions: (1) [Post Admission Cognitive Therapy (PACT) + Enhanced Usual Care (EUC)] or (2) Enhanced Usual Care (EUC). Individuals randomized into PACT+EUC will participate in the study assessments, receive six 60-90 minute individual face-to-face PACT psychotherapy sessions provided during their inpatient stay, up to a maximum of four 60-minute phone PACT booster sessions during the 3 months post hospital discharge, and case management services for 12 months. Individuals randomized into the control condition (EUC) will not receive the study intervention; they will receive the usual care provided in the inpatient setting, participate in study assessments, and receive case management services for 12 months. Patients in both conditions will be assessed on the dependent measures at baseline and at 1, 3, 6, and 12-month follow-up intervals.

**Relevance:** Delivering a brief and possibly potent psychotherapeutic intervention during a psychiatric inpatient hospitalization followed by an aftercare component aims to directly target individuals at high risk for future suicide behavior, specifically young, psychiatrically hospitalized adults under the direct stress of a military career. The development and empirical validation of an inpatient cognitive behavioral treatment is a significant endeavor in our national as well as Department of Defense (DoD) suicide prevention efforts. If *Post Admission Cognitive Therapy* is found to be efficacious, the intervention can be subsequently disseminated to inpatient settings as the standard of care for military personnel admitted for suicide-related events.

## Body

During each quarter of the past year, we engaged in the following activities: (1) working directly with the Henry Jackson Foundation (HJF) to ensure the timely processing of the sub-awards and contracts for the study (Denver VA; Duke University; KAI, Inc.; University of Michigan; and University of Pennsylvania); (2) working directly with the regulatory boards at the Uniformed Services University of the Health Sciences (USUHS), Walter Reed National Military Medical Center (WRNMMC), Ft. Belvoir Community Hospital (FBCH), Duke University IRB, Michigan University IRB, and the Human Research Protections Office (HRPO) at the USAMRMC Office of Research Protections to prepare all required IRB-related documentation; (3) continuing the process of new employee selection and recruitment; (4) providing training to newly hired staff; (5) coordinating with various study collaborators on research efforts; (6) purchasing study-related materials and supplies; (7) refining the baseline and follow-up assessment protocols, standard operating procedures, and treatment protocols; (8) maintaining regular contact with collaborators at Duke University, Denver VA, University of Michigan, and University of Pennsylvania; and (9) working with the KAI team to develop electronic study related forms and questionnaires, problem solving study-related challenges, and planning for the adverse event reporting/tracking for the multi-site RCT.

**Quarter 1:** During the first quarter of Year 2, we were met with a number of challenges associated with the Base Realignment and Closure (BRAC). The BRAC transition resulted in a need for us to establish a new procedure for conducting research at WRNMMC. All the infrastructure setup previously at the Walter Reed Army Medical Center (WRAMC) as a foundation for our work on this study has been lost. There were new staff, new offices, and new policies at the WRNMMC which required additional time to establish the infrastructure needed for this research. This, of course, was not expected at the time of the writing of the funded grant application and not taken into account in terms of our study timeline. For example, we have had to start with a new system for VPN (Virtual Private Network) and Essentris (i.e., inpatient electronic medical record) access. We have had to alter our plans for the requesting of department approvals on Impact Statement documents required by the WRNMMC IRB. The PI met with the head of the WRNMMC inpatient psychiatric unit, Geoffrey Grammer, MD, on April 25, 2012 in order to discuss and collaborate on a new policy for patient referral and consent into the study. Goals were set to develop a streamlined process of patient assessment and referral in an effort to increase patient recruitment.

An additional accomplishment for the first quarter was receiving research support letters from FBCH. The study PI had approached Dr. Jennifer Weaver who is serving as the Chief of Inpatient Psychiatry at FBCH inpatient psychiatric unit to discuss the feasibility of recruiting study participants from that site. Dr. Weaver was previously involved with our pilot trials performed at WRAMC and has been very eager and excited to have our research team become involved in the new unit at FBCH. On February 15, 2012, we received a letter of support from Dr. Weaver and she has provided approval for participant recruitment at FBCH. Given the expected IRB delays for the Portsmouth site and the oversight of FBCH regulatory issues by the WRNMMC IRB, a decision was made to instead use the FBCH site as the second site for the recruitment of study participants.

**Quarter 2:** During the second quarter of Year 2, the study PI presented at the “In Progress Review” Meeting held at Ft. Detrick, Maryland on May 16-17, 2012. Please see Appendix A for a copy of this presentation.

**Quarter 3:** During the third quarter of Year 2, the study PI held weekly “Clinical Trial Management Meetings” during which time she met with the research staff at USUHS to discuss issues pertaining to the daily execution and management of study related activities. Meeting sessions were used to problem solve research-related obstacles and implementation related issues during the pilot trials and how that will directly impact the PACT RCT implementation. In addition, weekly “PACT Treatment Meetings” were held with doctoral level clinicians to discuss active patient cases on the PACT pilot studies (currently underway) which also involved listening to digital recordings of therapy sessions and/or reviewing of typed transcribed sessions for the purposes of treatment adherence, refinement, and integrity. The doctoral level clinicians are also being trained in the use of the Cognitive Therapy Rating Scale (CTRS) in order to finalize the integrity and competency rating scale, as outlined in the Statement of Work for Year 1. Discussing active patient cases also contributes to the development of the PACT Treatment Manual. The PI and study staff members have also met periodically with the KAI staff as well as maintained phone and email communication with off-site collaborators to update them of the progress being made with the regulatory board/IRB phase of the project.

An additional challenge during the third quarter was the continued issue of establishing research infrastructure at the WRNMMC site. After the Base Realignment and Closure, there was not a clearly defined process of obtaining hospital credentials and renewing hospital credentials for “research” personnel. An email sent from the study PI to the Chair of the WRNMMC IRB (see below) summarizes some of the key issues involved:

“I am planning to discuss these issues with a USUHS Office of Research Representative and a HJF Representative in order to make sure that all USUHS faculty including myself are following the procedures in the correct manner. I appreciate your help in providing guidance on these issues. I want to make sure that I adequately problem solve some of the credentialing issues that my staff and I have been facing in the conduct of our research protocols at WRNMMC.

1. Does a USUHS PI on a WRNMMC IRB-approved study require to be credentialed as a provider at WRNMMC?
2. Does the WRNMMC IRB recognize that credentialing of a USUHS PI at WRNMMC NOW requires direct patient care by the study PI?
3. What are the specific WRNMMC IRB regulations and/or policies regarding credentialing, pertaining to USUHS/HJF research assessors and/or clinicians who deliver services to WRNMMC study participants/patients? Is it a requirement for research study assessors and therapists to be credentialed at WRNMMC?
4. What are the specific WRNMMC IRB regulations and/or policies regarding credentialing, pertaining to USUHS/HJF research staff who interact with study participants in a non-clinical

manner, e.g., working with a participant on informed consent, conducting follow-up telephone assessment at the USUHS site?

5. In terms of documentation, are WRNMMC research staff advised to place clinical notes in the participants'/patients' ESSENTRIS and/or AHLTA records? Has the WRNMMC IRB discussed the complex ethical issues related to keeping research and clinical care documents separate?

6. IF credentialing of all research staff is required, WRNMMC credentialing office will NOT renew privileges unless a peer review can be conducted. However, as it currently stands, peer review is based on a review of medical documentation in the patient's chart. Researchers who DO NOT record information in a patient's medical record in order to maintain confidentiality of the participant and in order to keep research and medical records separate do not seem to have an option for getting peer reviewed. Therefore, this lack of documentation makes it impossible for peer review at the time of credentialing renewal. To date, no procedures for peer review of research records exist, to the best of my knowledge (unless we count an IRB audit as a research review). I understand that these questions may be difficult to address via email. If you prefer that we setup a meeting to discuss, I would be available to meet and I would very much appreciate your guidance. Over the past six years, I was very clear about credentialing expectations at WRAMC given the clear guidance that was provided to me. However, I remain very unclear about these issues given the new WRNMMC formation. I have now met twice with the Chief of Psychology and the Chief of Credentialing at WRNMMC. Unfortunately, much ambiguity continues to exist about these issues and I am not certain about how to best address these issues responsibly in the context of my studies at WRNMMC. Thank you again for your time and guidance.”

Despite the credentialing situation which shut down our pilot trial activities on PACT, we continued to move forward with the setup for this proposed study. IRB approval for the project was obtained from the WRNMMC IRB on October 2, 2012. We subsequently held a conference call with Marianne Spevak and Julie Lee from the Regulatory Office at HJF to discuss the Duke University approval process for the protocol. A major concern was related to the potential delays involved in going back and forth between the WRNMMC and Duke IRBs. We explored various options to the regulatory process, one of which was to obtain the Duke IRB deferral to an IRB with the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). On November 1, 2012, the Study PI and clinical coordinator participated in a conference call with the Duke Site PI, Dr. David Goldston, the Duke IRB Executive Director, Jody Power, and Marianne Spevak and Julie Lee from HJF. The Duke IRB assured us that, in part because Duke was not recruiting patients, their review would focus on the Duke protocol rather than the WRNMMC approved protocol and consent form, and therefore, they would most likely only request changes to the Duke protocol. The group consensus was to use the Duke IRB as the Duke site's IRB of record.

**Quarter 4:** During the fourth quarter of Year 2, much progress was made on the regulatory review process for the study. On December 7, 2012, the USUHS IRB issued a secondary concurrence letter for the study. On December 14, 2012, the Duke IRB provided approval for the planned study. On December 19, 2012, we obtained approval from HRPO. On October 2, 2012, the WRNMMC IRB approved the implementation of the study at the FBCH site. On January 3,

2013, a letter of endorsement was issued by the Ft. Belvoir research office. On November 27, 2012, the original submission to the Michigan University IRB was made and approved.

In addition, on November 28, 2012, the USUHS research team travelled to FBCH and met with the staff to discuss setting up the study and beginning recruitment. Introduction of staff and logistical matters were discussed. Dr. Weaver and the FBCH staff expressed their continued support and were eager to begin research. The study PI has reached out the Office of Research and the Credentialing Office at FBCH in order to determine the procedures required for the setup of research personnel at their military treatment facility. Final decisions on this matter are pending but are hoped to be resolved during the next quarter.

Several other weekly meetings were held during this quarter, including (1) an assessment meeting to continue developing the database, (2) a manuscript meeting to work on publishing a case study using the PACT intervention, and (3) the monthly Research Round Table, at which the Clinical Coordinator gains information about and maintains communication with the WRNMMC IRB.

Several trainings were held to train staff for the upcoming recruitment, including a three hour PACT Training by the study PI to train study clinicians on the intervention, held on January 4, 2013 and a two hour conference call training on Motivational Interviewing to Address Suicidal Ideation (MI-SI): Motivating People to Live by Peter C. Britton, PhD from the Canandaigua VA Medical Center, Center for Excellence, held on January 10, 2013.

The WRNMMC IRB and Credentialing Office requested that the study PI (given her lapsed privileges at WRNMMC due to the absence of medical records for peer-review – given the purely research nature of contact with study participants) identify a credentialed site PI for the WRNMMC and FBCH sites. On December 17, 2012, we submitted an amendment naming Dr. Geoffrey Grammer (Chief of Inpatient Psychiatry) as the Site PI for WRNMMC and Dr. Jennifer Weaver (Chief of Inpatient Psychiatry) as the Site PI for FBCH and having Dr. Holloway listed as the overall study PI. By the end of this reporting period, this amendment still has not been approved. We hope to secure approval during the next quarter. We will continue to problem solve challenges as they arise to ensure that our study objectives are met within a reasonable and timely manner. The goal is to begin recruitment of several pilot/training cases during the next quarter in order to problem solve any potential challenges before the formal launch of the study recruitment for the multi-site RCT.



A brief summary of the progress made on all Year 2 tasks listed on the original Statement of Work is provided below.

### **Overview of Study Activities for Quarters (Q) 1-4**

**Performance Period: February 1, 2012 to January 31, 2013**

#### **1. Begin recruitment of training cases (as needed) and study participants at Site 1 (WRAMC) (Q 5)**

Please note that recruitment has not yet begun due to encountered delays in the regulatory review process for this study as well as the initial base realignment and closure related delays during Year 1 of the study. During the next quarter, we plan to begin with the recruitment of training cases. Therefore, we are approximately one year behind on this specific activity.

The initial submission to the WRNMMC IRB (lead site) was made on June 5, 2012. On June 20, 2012, the IRB requested 5 minor modifications be made to the consent and protocol to clarify the language. These modifications were made and the project was resubmitted on July 27, 2012. The WRNMMC IRB approved the modifications on October 10, 2012. After receiving approval from the primary IRB, on November 26, 2012 we submitted to the USUHS IRB for secondary concurrence, which was provided on December 7, 2012. The Duke site received initial approval for the project from the Duke University IRB on December 14, 2012. HRPO then provided initial approval of the project on December 19, 2012. We submitted an amendment to name and clarify the roles of the site PIs and study PIs on December 17, 2012. By the end of this reporting period this amendment still had not been approved. We hope to secure approval during the next quarter. We submitted the protocol for the FBCH recruitment site on January 3, 2013. As of the end of the reporting period, the protocol had been forwarded to the WRNMMC IRB, which reviews protocols for FBCH, because FBCH does not have its own IRB. We anticipate receiving approval for the FBCH site early in the next reporting period.

#### **2. Activate study website for follow-up web assessments (Q 5)**

Based on information gathered during the pilot trials, we have had very low usage and compliance with the web-based assessment option at the time of follow-ups. Therefore, in order to manage funds effectively and to ensure effective coverage for telephone follow-up assessments (which appears to be the most acceptable and feasible for study participants based on preliminary data), we have decided not to use web-based assessments for this multi-site study.

For data storage and security, follow-up assessment data will be entered into a secure website portal into the KAI database. Twenty-seven forms were created in the KAI database. An additional seven forms were revised. KAI sent USUHS Client Approval Packets including an approval form, the eCRF screens, and the edit specs on April 9, June 7, and November 30 which incorporated a total of 31 forms for approval. Twelve additional forms are pending. As requested, KAI delivered the remote desk application to the USUHS team on April 25 which links to the test version of the database. This file provides the study team access to the database during the development phase allowing them to maneuver through and become familiar with the system prior to the “go live” date.

### **3. Begin recruitment of training cases (as needed) and study participants at Site 2 (NMCP) (Q 6)**

Please note that recruitment has not yet begun due to encountered delays in the regulatory review process for this study as well as the initial base realignment and closure related delays during Year 1 of the study. During the next two quarters, we plan to begin with the recruitment of training cases at the second site. Therefore, we are approximately one year behind on this specific activity.

Due to the expected lengthy delays in the regulatory review processes for NMCP, we made a decision to change our second recruitment site from NMCP to FBCH. We are currently also investigating the possibility of adding a third site to the study in order to increase our enrollment timeline and to expand the study to a sample of Veterans at the Durham VA. Please note that the statement of work for the study remains unchanged as the number of participants to be recruited within this multi-site trial still remains 218.

Our team members visited FBCH in May 2012 and November 2012 to meet with the inpatient psychiatry staff, tour the facilities, and to problem solve implementation obstacles. During the current reporting period, we have been in regular email and phone contact to continue to discuss and problem solve implementation issues. We have registered our study staff for the hospital orientation to complete all requirements before beginning patient recruitment. Several staff members have already completed this orientation procedure. However, we are currently in the process of gaining a better understanding of the credentialing and checking-in procedures for our research personnel to be housed at FBCH. Given the difficulties we have encountered at WRNMMC regarding the credentialing matter, we wanted to be in open communication with the Credentialing Office at FBCH and obtain clear instructions on their requirements before we begin recruitment. The study PI has been in communication with Karen S. Marshall, CPMSM, CPCS, Chief of Clinical Staff Services (Credentials) and LTC MeLisa Gantt, PhD, Chief of the Department of Research Programs at FBCH to address the credentialing matter and share our experience at WRNMMC. The hospital points of contacts are not very clear about these procedures for research personnel – e.g., whether there is a need for credentialing, registration as hospital volunteers. We hope to have this issue resolved over the next quarter.

We submitted required documentation to WRNMMC IRB for approval to add FBCH as a recruitment site. LTC Melisa Gantt, Chief of FBCH Research Programs, published an Endorsement Letter indicating that she is aware of the project and will be obtaining approval from the Hospital Commander at FBCH, once the IRB package is approved. As of the end of this reporting period, the IRB package had not yet been approved. We hope to secure approval in the next quarter and obtain a Start Letter, signed by the FBCH Hospital Commander, verifying that we may begin recruitment at FBCH.

### **4. Conduct follow-up phone and web-based assessments (Q 5-8)**

Follow-up assessments have not been completed given that study enrollment has not been initiated.

## **5. Offer study case management (Q 5-8)**

Case management services have not been offered given that study enrollment has not been initiated. However, we have generated a preliminary outline of case management services to be provided to study participants and are in the process of preparing a manualized case management guide.

## **6. Conduct competency and adherence ratings (Q 5-8)**

Competency and adherence ratings have not been completed given that study enrollment has not been initiated. During the past year, we have consulted with several collaborators on the study about the adherence rating form. We have developed a PACT version of the Cognitive Therapy Rating Scale to be used as a fidelity measure for the study.

## **7. Attempt to meet a “set” recruitment goal (Q 5-8)**

Not applicable. Study enrollment has not been initiated. We are currently working on adding a third recruitment site to the study in order to do some catching up – given that we are about a year behind on the original study timeline.

## **8. Setup Year 2 annual meeting for study collaborators (Q 7-8)**

We did not set up an on-site meeting for study collaborators during the past year in order to use the study funds wisely given the lengthy regulatory review processes. The PI has maintained regular face-to-face, email, and/or phone communication with key study collaborators, primarily to establish the infrastructure for our planned research. The other sites have had to wait for the WRNMMC approval of the Master Study Protocol before submitting their IRB application to their institution. Therefore, much of the work performed at the Denver VA, Duke University, and University of Michigan sites have been minimal to this point but we expect that, now that the Master protocol has received initial approval from the WRNMMC IRB, during the next quarter, the activities at these sites will increase to meet the study needs.

An in-person meeting has been scheduled for study investigators during the next quarter on February 21, 2013 at USUHS to prepare for the initiation of study recruitment and to problem solve any remaining issues. We will also make use of this time by having our collaborators at the University of Michigan provide training on motivational interviewing and the aftercare PACT booster sessions to study clinicians and research personnel in preparation for recruitment.

## **9. Hold Year 2 DSMB annual meeting (Q 7-8)**

We have not formed a Data Safety Monitoring Board (DSMB) given the regulatory review delays for the study. We have identified potential members for the DSMB. This list will be reviewed and solidified during the upcoming on-site investigator meeting to be held in February 2013. The first DSMB meeting will be held during Q1-2 of the third year prior to the formal initiation of the multi-site study.

## **10. Prepare and submit all applicable quarterly and annual reports (Q 5-8)**

We submitted Q1 and Q3 quarterly report on-time to the sponsor. Quarter 2 report received a waiver due to the study PI's presentation at the "In Progress Review" meeting held at Ft. Detrick, MD. See Appendix A for slides.

### **Additional Study-Related Activities**

#### **Obtained approval for the Data Sharing Agreement Application (DSAA)**

We gained authorization to access data from the DMSS. The Armed Forces Health Surveillance Center (AFHSC) has agreed to provide us with data from the Defense Military Surveillance System (DMSS) for our participants for the two years following their participation in the study. In order to obtain authorization to access the data, we submitted the WRNMMC IRB Approval letter, the DSAA to Ms. Barbara Hazzard at the TRICARE Management Activity (TMA) Privacy and Civil Liberties Office, and have answered specific questions and concerns that she raised. Ms. Hazzard granted approval on November 30, 2012.

#### **Preparation of Cooperative Research and Development Agreement (CRADA)**

The WRNMMC IRB has informed us that the previously submitted CRADA before the BRAC is now null and void. We have followed the guidance of the WRNMMC IRB to complete the new procedures required for the processing and approval of the CRADA. We submitted an Agreements Request form between WRNMMC and USUHS to store data on USUHS computers in October, 2012. The clinical coordinator and the Study PI has been in contact with Alan Cash in the Office of Research and Technology Applications at WRNMMC several times over the past year, providing updated information such as the Collaborative Research Letter, Award Letter, and Subawards for Duke, KAI, and University of Michigan and requesting clarification on how to move forward with the CRADA. As of the end of this reporting period, a CRADA has not been finalized.

#### **Attended IRB Research Round Table Meetings**

The study Clinical Coordinator attended WRNMMC "Research Roundtable" meetings, and gained important information about the current status of the WRNMMC IRB after the Base Realignment and Closure, including:

For the fiscal year 2012 there were approximately 1700 "actions" submitted to the WRNMMC IRB, which includes continuing reviews, amendments, etc. This equates to approximately 150 a month. There are 970 open protocols. This may provide insight into why reviews are usually delayed. The WRNMMC IRB reported the following information regarding duration of review:

- New reviews take approximately 150 days
- Expedited Reviews take approximately 100 days
- Continuing reviews or amendments take approximately 60 days
- Duration depends on when during the month you submit
- Takes even longer if the protocol is "greater than minimal risk" whereby the admiral needs to sign the minutes from the IRB review meeting

#### **Attended the 2012 DoD/VA Suicide Prevention Conference**

The PI was an invited presenter at the June, 2012 DoD/VA Suicide Prevention Conference in

Washington, DC during which time she provided an 8 hour training session for cognitive therapy for suicidal patients. Study staff attended the meeting as well. The meeting consisted of a variety of presentations offered by nationally known suicidology experts who discussed issues relevant to suicide, specifically in a military context. The forum provided the PI and the study personnel with an opportunity to learn about the details of other clinical research (e.g., caring letters, outpatient cognitive therapy for suicide prevention), to network with experts in the field, and to learn from family members/survivors of military suicide.

### **Participated in the In-Progress Review (IPR) and North Atlantic Treaty Organization (NATO) Meetings**

The study was presented at the IPR annual meeting held in Ft. Detrick, MD during May, 2012. This provided an opportunity to exchange ideas with other investigators involved in military suicide prevention research. The NATO meetings were chaired by the study PI during which time the topic of military suicide across various NATO and partner countries was discussed. Attendance in these meetings were not supported by funding provided by this grant – however, the knowledge gained has been valuable in better understanding the unique needs of this highly vulnerable military population and the best practices employed by other nations.

### **Maintained Communication with Medical Monitor**

Russell B. Carr, MD, Chief, Adult Outpatient Behavioral Health Clinic, at WRNMMC was appointed to be the Medical Monitor for the study in December, 2011. The study PI has had ongoing communication with Dr. Carr in order to review the role and responsibilities of the Medical Monitor and to answer any questions. Dr. Carr is extremely supportive of our efforts and has kindly volunteered his time to serve in this capacity.

### **Explored Adding an Additional Site at the Durham VA**

The study investigators have discussed the possibility of adding a third site for study recruitment in order to make faster progress on the study timeline (given the extensive BRAC and regulatory related delays). Two sites under consideration have been the Denver VA and the original Portsmouth Naval Medical Hospital. However, these two sites present a number of challenges. The Denver VA site is already engaged in a number of studies – one of which is based in the inpatient psychiatric unit. The Portsmouth site has demonstrated regular staff turnover and does not offer the opportunity to connect with a research-oriented site PI in addition to presenting a number of regulatory board challenges. Most recently, Dr. Goldston, the Duke University Site PI, suggested the addition of the Durham VA as a study site. After careful consideration and discussion among study investigators, group consensus remains that the addition of a VA site will be advantageous in providing more generalizability to our study findings. Moreover, the addition of a site so close to the Duke University site (which serves as the follow-up assessment core for this study) will also be desirable due to the solid leadership of Dr. Goldston and his strong connections with the Durham VA staff. Dr. Goldston plans to meet with several colleagues at the Durham VA during the next quarter to discuss expanding to this site. The results of the meeting will be reported in the next quarterly report.

### **Updated ClinicalTrials.gov Entry**

The study PI has regularly updated the ClinicalTrials.gov entry for this multi-site RCT.

## **Site Specific Reports of Activities in Collaboration with USUHS Team**

### **KAI Research, Inc. (KAI)**

#### **A. Introduction – Contract Primary Objectives and Tasks**

KAI as the Data and Statistical Coordinating Center (DSCC) is responsible for providing coordination, data management, monitoring, and logistical support for the PACT study.

#### **B. Brief Narrative of Tasks Accomplished**

1. Database Development – Twenty-seven forms were created in the KAI database. An additional seven forms were revised. KAI sent USUHS Client Approval Packets including an approval form, the eCRF screens, and the edit specs on April 9, June 7, and November 30 which incorporated a total of 31 forms for approval. Twelve additional forms are pending.
2. Database Access –
  - a. KAI delivered the remote desk application to the USUHS team on April 25 which links to the test version of the database. This file provides the study team access to the database during the development phase allowing them to maneuver through and become familiar with the system prior to the “go live” date. Since the delivery of the remote desk top application, KAI has worked with USUHS staff to ensure it is accessible and functioning properly for each individual user.
  - b. KAI trained 3 USUHS staff members during this reporting period on the data entry functions and capabilities of the database.
3. Study Forms – KAI suggested revisions to some forms by providing customized examples. The following forms were sent to USUHS for consideration: Medical History, Family History, Inclusion/Exclusion, Prior Medications, Concomitant Medications, Concomitant Therapies, Adverse Events, Study Completion, and Telephone Contact Log. KAI also sent information for the creation of a Behavioral Observations form.
4. Safety Reporting – KAI reviewed the safety reporting forms and guidelines for all sites provided on January 3 by the USUHS team. Together with Dr. Holloway and team we will create a process for Safety Reporting to all applicable oversight bodies.
5. Team Meetings - KAI provided agendas and meeting minutes for teleconferences conducted on February 3, March 9, March 30, May 11, June 8, July 13, August 10, September 7, September 21, October 5, November 2, November 30, December 14, and January 11. KAI hosted an in-house meeting and database training with the USUHS team on April 11 and distributed a list of action items to all meeting attendees.
6. Project Management - Celeste Crouse, the KAI project manager performed the following duties: served as the first line of contact for USUHS, supervised the entire KAI study team, and ensured that all deliverables to date were provided on time and of the highest quality. Amy Price is supervising form creation and database development.

**University of Michigan (Site PI: Cheryl King, Ph.D.)**

1. Obtained IRB approval for involvement in initial developmental phase of research project from the University of Michigan (UM) Medical School IRB (IRBMED).
2. Reviewed PACT protocol, including proposed baseline and follow-up assessment instruments, procedures, and timelines; Discussed these measures with UM co-investigators, Mark Ilgen, Ph.D., Paul Pfeffer, M.D., and Steve Chermack, Ph.D.; As a group, we reached a consensus on additional measures to propose for inclusion, which would assess areas related to social support and integration, use of prescription drugs, readiness to engage in treatment, and personal expectations regarding safety from self-harm. Additional research on these measures was conducted and we shared information with the PACT project leadership and team. As a group, final decisions were made regarding assessment instruments and timelines via conference call.
3. Developed draft protocol for PACT telephone booster sessions for review and discussion with PACT leadership team. This involved (a) completing review of recent literature and published guidelines regarding telephone continuing care treatment, telephone booster sessions, and telephone-based case management in the treatment of adults with mental disorders, alcohol/substance use disorders, and related conditions; (b) group meetings with UM team to discuss and develop multiple initial drafts of protocol (goals, timeline for sessions, orientation to aftercare phase, session outlines) for review and input; and (c) group meetings with UM team to develop a draft Progress Assessment Form/aftercare action plan to be completed by the PACT clinician during telephone booster sessions.
4. Contributed to development of case management protocol, including dose (amount) and duration of case management to be offered to all study participants in both treatment arms.
5. Participated in Project Conference Calls with PI, Marjan Holloway, Ph.D., Co-Investigator, David Goldston, Ph.D., and key members of study team to discuss IRB applications, the timeline and plan for piloting telephone booster sessions, and a wide range of study issues.
6. Reviewed protocol and clinical documentation forms for PACT telephone booster sessions, making final edits. Developed draft versions of fidelity assessment tools for review at PACT Grant meeting with project leadership. These involved: (a) group meetings with University of Michigan team to discuss and fine-tune protocol and associated documents; (b) conference calls with project leadership to discuss feedback and incorporate input.
7. Developed draft plan for provision of clinical training to therapists who will implement PACT telephone booster sessions, including in-person training and plan for fidelity assessment and follow-up supervision/consultation.
8. Submitted IRB amendment to UM to enable our involvement in subject recruitment and implementation phase of study.

### **Duke University (Site PI: David Goldston, Ph.D.)**

1. Participated in regular conference calls with key study collaborators and contributed to the discussions on research design, baseline and follow-up assessment batteries, retention strategies, risk management, and other implementation related issues
2. Prepared and submitted all applicable quarterly and annual reports for Duke University site to HJF and the sponsor in coordination with the USUHS team
3. Began discussions with the Durham VA regarding the possibility of adding the site as the third recruitment site for the study
4. In collaboration with USUHS study PI and KAI, reviewed computerized study forms and electronic data entry forms and provided feedback
5. Began to prepare follow-up assessment guide and training procedures
6. Discussed training and risk management procedures to be used for Duke assessors who will be responsible for the blind follow-up assessments
7. Prepared and submitted applicable IRB amendments in coordination with USUHS team

### **Denver VA (Site PI: Lisa Brenner, Ph.D.)**

1. Gained Clarification on Regulatory Procedures- Drs. Brenner and Matarazzo received guidance from their local IRB (Colorado Multiple Institution Review Board) and VA R&D stating that there is no need to submit a protocol regarding their role as consultants in this research project.
2. TBI Assessment Training Provided to Study Staff - Dr. Brenner conducted two presentations to USUHS staff regarding traumatic brain injury (TBI), with a specific focus on screening, assessment and intervention. Drs. Brenner and Matarazzo continue to train the USUHS team on the administration, coding, and interpretation of the Ohio State University TBI Identification Method, which will be used in the trial. Following the presentation of didactic information, USUHS staff completed case vignette scoring of the OSU TBI-ID. Dr. Matarazzo scored staff responses and provided written feedback.
3. Drs. Brenner and Matarazzo will continue to train USUHS staff on assessment and screening related to TBI. They will be available for consultation as the study moves closer to commencing. Additionally, as the study begins, they will review completed TBI assessments to ensure that they are being administered properly. Finally, they will provide study staff with additional resources to facilitate treating those with a history of TBI.



## **Key Research Accomplishments**

The key research accomplishments over the past year include the following:

- ☑ Receipt of regulatory approvals on the study protocol from various boards
- ☑ Finalization of the study baseline and follow-up assessment battery and procedures
- ☑ Manualized first drafts of study intervention, case management, and risk management
- ☑ Creation of study web-based electronic forms and database
- ☑ Training of personnel on assessment and intervention procedures
- ☑ Problem solving of implementation challenges and plans to add 3<sup>rd</sup> recruitment site
- ☑ Dissemination of information about PACT via national and international presentations

Given the magnitude of the public health problem of military suicide and the increasing rates of psychiatric hospitalizations within DoD, the development and empirical validation of an inpatient cognitive behavioral treatment is a significant suicide prevention endeavor. Delivering a brief and possibly potent psychotherapeutic intervention during a psychiatric inpatient hospitalization followed by an aftercare component aims to directly target individuals at high risk for future suicide behavior, specifically young, psychiatrically hospitalized adults under the direct stress of a military career.

## Reportable Outcomes

### **Section I. Manuscripts, Abstracts, Presentations**

No manuscripts that are directly supported by this award have been submitted to date. The following list provides invited as well as national and international presentations based on work supported by this award:

1. **Ghahramanlou-Holloway, M.** (2011, February). Post Admission Cognitive Therapy (PACT) for the inpatient treatment of military personnel with suicidal behaviors: A multi-site randomized controlled trial. Invited presentation at the United States Medical Research and Materiel Command 'In Progress Review' Meeting, Frederick, MD.
2. **Ghahramanlou-Holloway, M.** (2011, March). Evidence-based psychotherapy for suicide prevention: Practical tips from cognitive therapy. Invited presentation at the Annual Department of Defense and Veterans Administration Suicide Prevention Conference, Boston, MA.
3. **Ghahramanlou-Holloway, M.** (2011, March). Combat related trauma and suicide: Concepts of therapy. Invited symposium presentation with David Jobes and David Rudd at the 6<sup>th</sup> Aeschi Conference, Aeschi, Switzerland.
4. Szeto, E., Cox, D. W., Lou, K., Fritz, E., Engel, C., Bradley, J., Grammer, G., Wynn, G., & **Ghahramanlou-Holloway, M.** (2011, March). Gender differences on childhood and adulthood traumas: Inpatients admitted to a military psychiatric unit for suicide-related thoughts and behaviors. Poster presented at the Annual Department of Defense and Veterans Administration Suicide Prevention Conference, Boston, MA.
5. †**Ghahramanlou-Holloway, M.,** & Branlund, S. (2011, April). Deployment-related factors, mental health, and suicide: Review of the literature. Paper presented at the North Atlantic Treaty Organization (NATO) Human Factors and Medicine 205 Symposium on Mental Health and Well Being across the Military Spectrum, Bergen, Norway.
6. **Ghahramanlou-Holloway, M.** (2011, May). Evidence-informed approaches for the assessment and treatment of suicide-related ideation and behaviors. Invited 2 day training workshop provided to providers in Denmark, Psychiatric Center, Copenhagen, Denmark.
7. **Ghahramanlou-Holloway, M.** (2011, July). Practical strategies for the assessment and management of suicidal patients. Invited presentation at the Malcolm Grow Medical Center, Andrews Air Force Base, MD.
8. **Ghahramanlou-Holloway, M.,** Vasterling, J. J., & Kester, K. E. (2011, December). Ethical challenges in the conduct of suicide prevention research with military populations. In L. Brosch (Chair), Protecting our volunteers and our nation: The ethical challenges of military research. Invited symposium presentation at the PRIM&R Advancing Ethical Research Conference, National Harbor, MD.
9. **Ghahramanlou-Holloway, M.** (2011, December). Post Admission Cognitive Therapy (PACT) for the prevention of suicide. Presentation at the Medical and Clinical Psychology Colloquium Series at Uniformed Services University of the Health Sciences, Bethesda, MD.
10. **Ghahramanlou-Holloway, M.** (2012, January). Clinical trials on Post Admission Cognitive Therapy (PACT) and Safety Planning for the prevention of suicide. Invited presentation, Duke University Suicide Prevention Research Conference Call.

11. **Ghahramanlou-Holloway, M.** (2012, February). Post Admission Cognitive Therapy (PACT) for the prevention of suicide. Invited presentation at the Clinical Psychology Colloquium Series at The Catholic University of America, Washington, DC.
12. †Brazaitis, K., Schendel, C., Lunt, R., DeYoung, K., & **Ghahramanlou-Holloway, M.** (2012, April). Measuring the lethality of suicide-related behaviors: A literature review. Poster presented at the Annual Meeting of the American Association of Suicidology, Baltimore, MD.
13. †MacIntyre, J. M., Neely, L. L., & **Ghahramanlou-Holloway, M.** (2012, April). Emotion dysregulation and suicide: Literature review and recommendations for research and clinical practice. Paper presented at the Annual Meeting of the American Association of Suicidology, Baltimore, MD.
14. **Ghahramanlou-Holloway, M.**, Fitek, D., Joiner, T., Jobes, D., & Rudd, D. (2012, April). Review of funded DoD suicide prevention inpatient psychotherapy clinical research trials. In P. Gutierrez (Moderator), Status of Department of Defense funded suicide research. Symposium presented at the Annual Meeting of the American Association of Suicidology, Baltimore, MD.
15. **Ghahramanlou-Holloway, M.** (2012, May). Post Admission Cognitive Therapy (PACT) for the inpatient treatment of military personnel with suicidal behaviors: A multi-site randomized controlled trial. Invited presentation at the United States Medical Research and Materiel Command 'In Progress Review' Meeting, Fort Detrick, MD.
16. Rodney, H., Carreno, J., Grammer, J., VanSickle, M., Blevins, C., & **Ghahramanlou-Holloway, M.** (2012, June). Mental health stigma and suicide prevention: Review and recommendations. Poster presented at the Annual Department of Defense and Veterans Administration Suicide Prevention Conference, Washington, DC.
17. Kochanski, K., Bemis, J., Perera, K., Deyoung, K., & **Ghahramanlou-Holloway, M.** (2012, June). Single vs. multiple suicide attempts in a psychiatrically hospitalized military sample. Poster presented at the Annual Department of Defense and Veterans Administration Suicide Prevention Conference, Washington, DC.
18. **Ghahramanlou-Holloway, M.**, Castro, C., Fitek, D., & Jobes, D. (2012, June). DoD funded inpatient psychotherapy randomized controlled trials for the prevention of suicide. In P. Gutierrez (Moderator), Status of Department of Defense funded suicide research. Symposium presented at the Annual Meeting of the American Association of Suicidology, Baltimore, MD.
19. Neely, L. L., Spangler, P., Schendel, C., Lunt, R., Grammer, G., & **Ghahramanlou-Holloway, M.** (2012, June). Post admission cognitive therapy following suicide attempt for active duty service members with PTSD: A case example. Symposium presented at the Society for Psychotherapy Research Annual Conference, Virginia Beach, VA.
20. **Ghahramanlou-Holloway, M.** (2012, June). Cognitive behavior therapy for the prevention of suicide. Invited 1-day pre-conference training session provided at the Annual Department of Defense and Veterans Administration Suicide Prevention Conference, Washington, DC.
21. **Ghahramanlou-Holloway, M.** (2012, August). Laboratory for the treatment of suicide-related ideation and behavior: Organization and current activities. Invited presentation at the Defense Suicide Prevention Office, Staff Educational Series, Arlington, VA.
22. George, B., Carlin, E., Testa, L., MacIntyre, J. M., & **Ghahramanlou-Holloway, M.** (2012, August). Gender differences in military psychiatric inpatients admitted for suicide ideation.

Poster to be presented at the Annual Meeting of the American Psychological Association, Orlando, FL.

23. Neely, L. L., & **Ghahramanlou-Holloway, M.** (2012, August). Post admission cognitive therapy (PACT) for the prevention for suicide in military personnel with histories of trauma: Treatment development and case example. Breakout session presented at the Military Health System Research Symposium, Ft. Lauderdale, FL.
24. **Ghahramanlou-Holloway, M.** (2012, September). Managing suicidal behaviors. Invited webinar presented with Dr. Peter Gutierrez, organized by the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury, podcast available by visiting (<http://www.dcoe.health.mil/Training/MonthlyWebinars/2012Webinars.aspx>)
25. **Ghahramanlou-Holloway, M.**, Jobes, D., Brown, G., Rudd, D., & Linehan, M. (2012, November). Evidence-based CBT approaches in inpatient care for suicide prevention. In K. Crowley (Chair), Cognitive and behavioral therapies for suicide: What do we know, and what makes them work? Symposium to be presented at the Annual Meeting of the Association of Behavioral and Cognitive Therapies, National Harbor, MD.

## **Section II. Funding Applied for Based on Work Supported by This Award**

None.

## **Section III. Research Opportunities Applied for and Received Based on Experience or Training Supported by This Award**

- |      |  |
|------|--|
| 2012 | PI was selected as Fellow to participate in a 2-week Summer Institute on Randomized Behavioral Clinical Trials, National Institutes of Health, Office of Behavioral and Social Sciences Research |
|------|--|

## **Conclusion**

There are no study findings to report at the present time. The second year of the study has continued to heavily focus on the following activities: (1) obtaining appropriate regulatory approvals; (2) setting up the infrastructure for the study implementation at the two study sites (Walter Reed National Military Medical Center and Ft Belvoir Community Hospital); (3) selecting, hiring, and training study personnel; (4) finalizing the study assessment batteries for baseline and follow-up; (5) coordinating and communicating with sites about study setup; (6) clarifying credentialing and staff start-up procedures at each military treatment facility; and (7) developing the study master database, randomization procedures, and electronic forms for web-access and entry. We expect to initiate study recruitment in Year 3.

The early study conclusions are that at least 12-18 months need to be devoted to obtaining regulatory approvals for research pertaining to suicidal individuals receiving treatment at a military treatment facility. In addition, credentialing issues at various military treatment facilities such as WRNMMC and FBCH for research personnel appear to remain unclear and present unique implementation and financial challenges for suicide prevention research within the DoD setting.

This study is responsive to the critical mental health care needs of military service members by providing a targeted cognitive behavioral intervention for suicide ideation and behavior severe enough to warrant psychiatric hospitalization. The ultimate goal of the treatment is to prevent suicide and associated risk factors within a high risk group of the Armed Forces. Without adequate treatment, suicide related events leading to psychiatric hospitalization may result in costly utilization of military, VA, and civilian health and social services, a decrease in operational readiness and morale, human suffering, and eventual death.

Furthermore, this study is aligned with several critical research areas recognized by the US Research and Materiel Command: (1) reduction of the impact of mental disorders for the Armed Forces; (2) development of strategies to enhance mental health and well-being throughout service members' careers; (3) validation of effective psychotherapy interventions; (4) targeted evidence-based risk reduction methods for suicide behavior; (5) development of valid treatment related outcome measures and tracking systems; (6) reduction of barriers to care and appropriate linkage to healthcare services; and (7) special considerations for sub-populations with unique needs – for instance, those with combat trauma and/or Traumatic Brain Injury (TBI).

## References

None.

## **Appendices**

### **Appendix A**

**“In Progress Review”, Ft. Detrick, Maryland  
Presentation Slides, May 17, 2012**

## Post Admission Cognitive Therapy (PACT) for the Inpatient Treatment of Military Personnel with Suicidal Behaviors: A Multi-Site Randomized Controlled Trial

Principal Investigator: Marjan G. Holloway, Ph.D.

Award Number: W81XWH-11-2-0106

Award Date: February 1, 2011

Award Amount: \$6,000,000

Contract Officer Representative: Ms. Amber Shryer

Project Officer: Ms. Ruchi Malik

Portfolio Manager: Dr. Diana Fitek



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*of the Health Sciences*

## Key Research Personnel

### Co-Principal Investigators (Alphabetical Listing)

**COL Charles C. Engel, M.D., M.P.H.**, Associate Professor & Associate Chair,  
USUHS Psychiatry; Director, DoD Deployment Health Clinical Center

**David Goldston, Ph.D.**, Associate Professor, Duke University

**Cheryl King, Ph.D.**, Professor, University of Michigan

### Co-Investigators (Alphabetical Listing)

**John Bradley, M.D.**, Chief of Psychiatry, Deputy Director of Mental Health, VA Boston

**Lisa Brenner, Ph.D., ABPP**, Director, VISN 19 Mental Illness Research Education & Clinical Center

**Gregory K. Brown, Ph.D.**, Associate Professor, University of Pennsylvania

**LTC Geoffrey Grammer, M.D.**, Chief, Inpatient Psychiatry, WRNMMC

**MAJ Gary Wynn, M.D.**, Research Psychiatrist, Walter Reed Army Institute of Research



## Inpatient Interventions

- Group Therapy
- Medication Management
- Art Therapy
- Physical Therapy
- Recreation Therapy
- Individual Therapy

None Targeted  
Directly at Suicide  
Ideation and/or  
Behavior

Hospitalization Cost After Suicide Attempt in 2005 Dollars (Yang & Lester, 2007)  
Average = \$13,690  
Range = \$1,997-\$68,150

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## Knesper (2011)

Report Commissioned by SPRC & SAMSHA

“Despite the centrality of hospitalizing seriously ill psychiatric patients, the research base for inpatient hospitalization for suicide risk is **surprisingly weak**. This review **could not** identify a single randomized trial about the effectiveness of hospitalization in reducing suicide acts after discharge.”

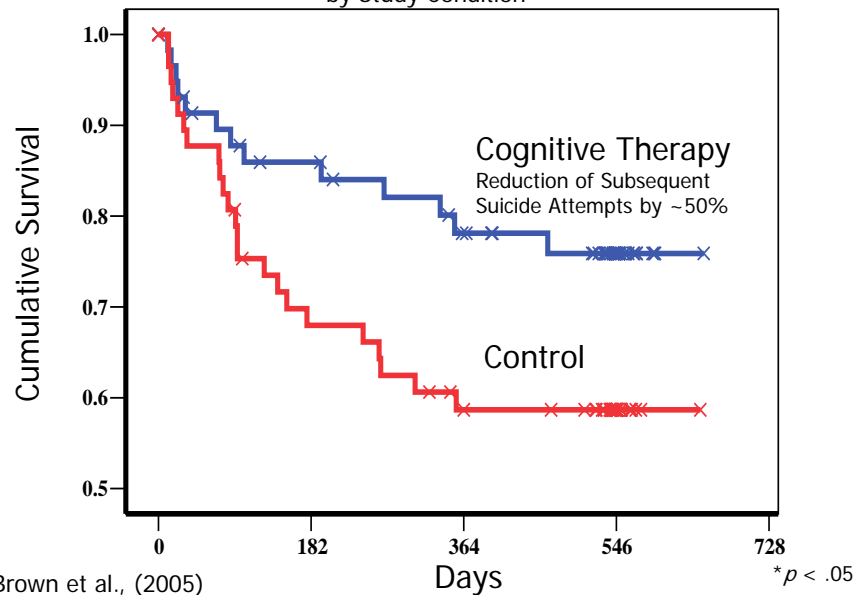
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## Inpatient Psychotherapy for Prevention of Suicide

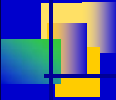
- **Study 1 (Lieberman et al., 1981)**
  - 24 Patients Randomized, 2 Yr Follow-up
    - Behavior Therapy (n = 12); Insight Oriented Therapy (n = 12)
  - 4 Daily Hours of Therapy over 8 Days
  - Outcomes: Depression, Suicide Ideation, & Attempts
  - BT > IOT at 9 Months
- **Study 2 (Patsiokas, 1985)**
  - 15 Patients Randomized, No Follow-up
    - Problem Solving (n = 5); Cognitive Restructuring (n = 5); Non-Directive Control (n = 5)
  - 10 Individual Sessions over 3 Weeks
  - Outcomes: Hopelessness, Suicide Ideation, & Intent
  - PS > CR

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**10-Session Outpatient Cognitive Therapy for the Prevention of Suicide**  
Survival Functions for Repeat Suicide Attempt  
by Study Condition



	<b>Trial 1 Stage I</b>	<b>Trial 2 Stage I</b>	<b>Trial 3 Stage II</b>
<b>Total Participants</b>	N = 24	N = 50	N = 218
<b>Recruited To Date</b>	<b>21</b>	<b>16</b>	<b>0</b>
<b>Funding Source and Amount</b>	National Alliance for Research on Schizophrenia and Depression \$60,000	Congressionally Directed Medical Research Program \$442,040	United States Department of Defense \$6,000,000
<b>Inclusion Criteria</b>	Inpatients  Suicide Attempt Admission	Inpatients  Suicide Related Admission Suicide Attempt (Lifetime) AND Trauma	Inpatients  Suicide Related Admission + Suicide Attempt (Lifetime)
<b>Intervention 6 Individual Sessions ~90 Minutes Each</b>	Post Admission Cognitive Therapy (PACT)	Post Admission Cognitive Therapy (PACT) - Trauma	Post Admission Cognitive Therapy (PACT) + Phone Booster Sessions
<b>Sites</b>	Walter Reed National Military Medical Center; Ft. Belvoir To Be Added: 1 VAMC; Naval Medical Center Portsmouth (?)		



## Study Primary Objectives

To evaluate the efficacy of PACT+EUC compared to EUC for the prevention of suicide in psychiatrically hospitalized military personnel at follow-up (1, 3, 6, and 12-month) on

**Objective 1)** Incidence of repeat suicide attempt(s) and number of days until a repeat suicide attempt (primary outcomes).

**Objective 2)** Psychiatric symptoms (depression, trauma, sleep, suicide ideation), repeat number of psychiatric hospitalization(s), hope for one's future, and acceptability of treatment (as measured by time to linkage to specialty care, attitudes toward seeking help for mental health issues, and subsequent mental health service utilization) (secondary outcomes).

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## Study Exploratory Objectives

- To examine whether improvements on primary and secondary outcome measures are associated with improved problem solving abilities (i.e., decreased avoidant and impulsive problem solving) which may be viewed as a potential mechanism of change in the reduction of suicide behavior.
- To examine whether the domains specifically and primarily targeted in the PACT booster session/aftercare component (i.e., readiness for engagement in recommended aftercare treatment) change during the booster session/aftercare phase and are associated with subsequent mental health service utilization.

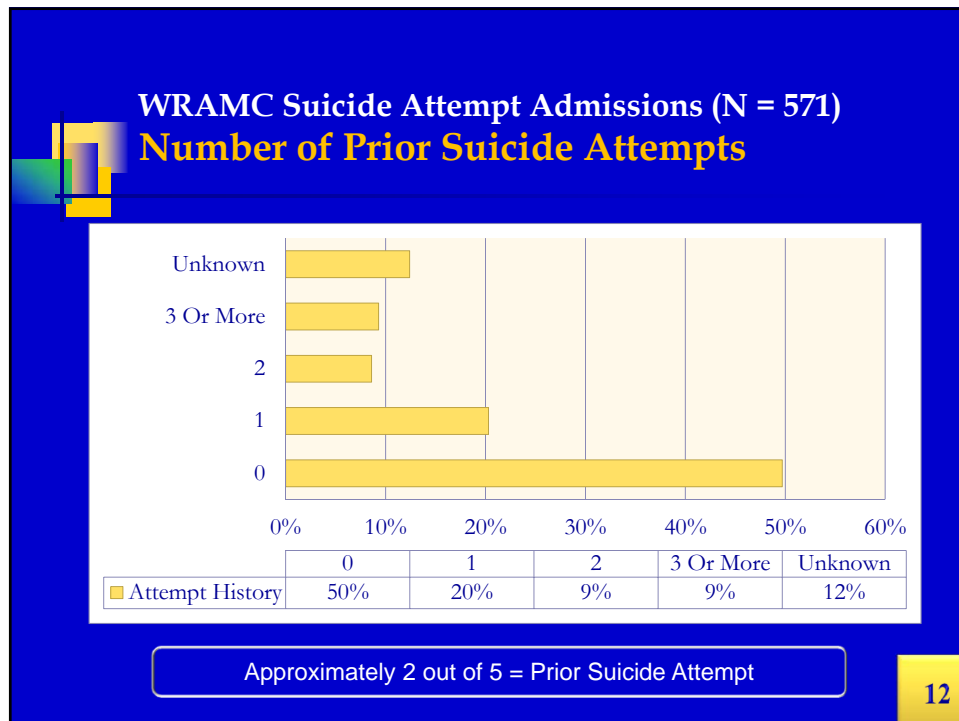
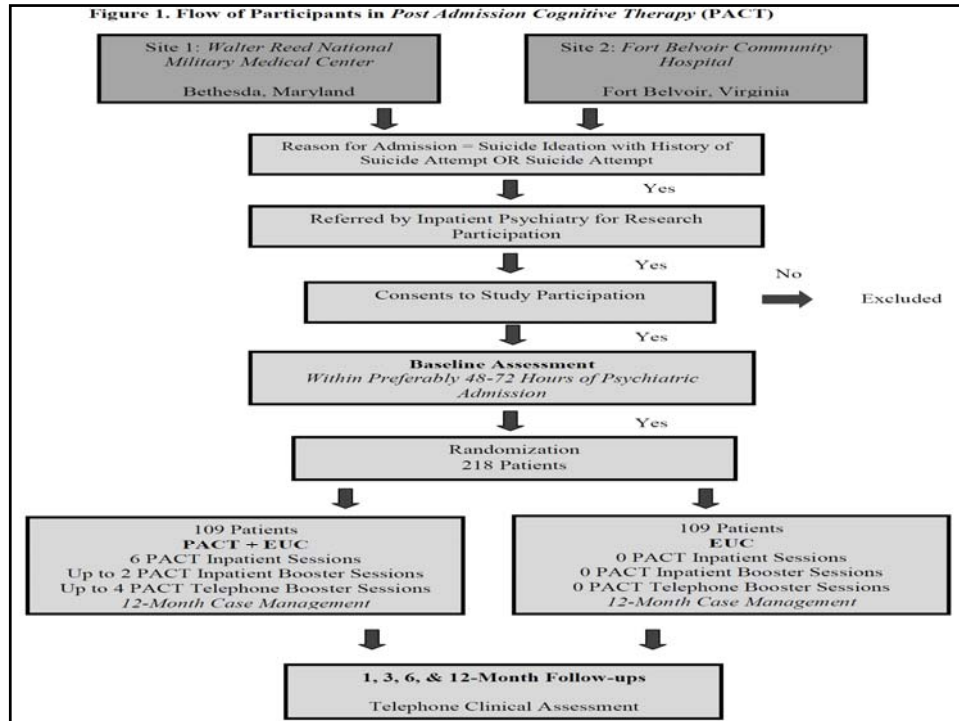
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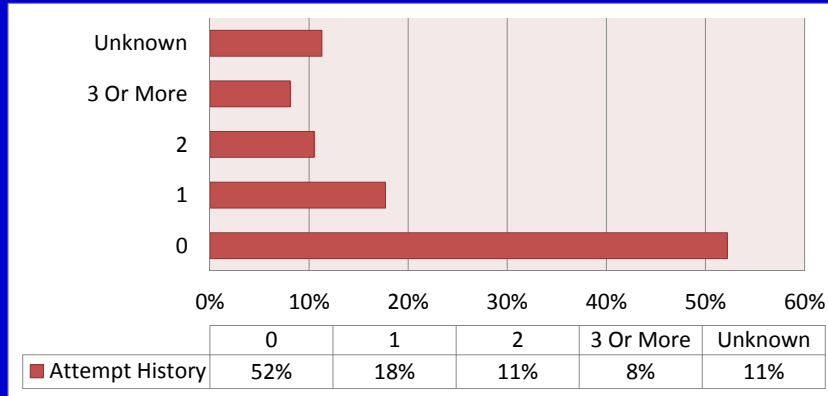
## Study Participants

- **Inclusion Criteria**
  - Suicide Ideation + Prior Attempt **OR** Recent Suicide Attempt
  - Baseline Completed within Preferably 48-72 Hours of Admission
  - Over the Age of 18
  - Provides Informed Consent
- **Exclusion Criteria**
  - Medical Incapacity to Participate
  - Serious Cognitive Impairment
  - Expected Discharge within 72 Hours of Admission

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## WRAMC Suicide Ideation Admissions (N = 638) Number of Prior Suicide Attempts



Approximately 2 out of 5 = Prior Suicide Attempt

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## Discharge Outcomes for Suicide Attempt versus Ideation Psychiatric Admissions at WRAMC (2001-2006)

Outcome	Suicide Attempt (N=571)	Suicide Ideation (N=638)
Discharge Home/Other Location	27.3%	26.6%
Return to Full Duty Status	29.2%	34.3%
Administration Separation	25.6%	23.8%
Medical Board Review	11.9%	12.1%
Partial Hospitalization Program	3.0%	1.6%
Unknown	3.0%	1.6%

$\chi^2(5, N=1209) = 8.228, p = 0.144 \rightarrow$  no differences in outcome

Average Length of Psychiatric Stay at WRAMC (SA Admission) = 8.72 Days (SD = 11.16)

Average Length of Psychiatric Stay at WRAMC (SI Admission) = 7.98 Days (SD = 7.71)

Average Length of Psychiatric Stay at Civilian Hospitals = 8.2 Days

## Enhancements Based on Pilot Trials

- Military AND VA Implementation
- 1-Year Case Management for ALL Study Participants
  - USUHS – Dr. Marjan Holloway & Team
- Follow-Up/Aftercare – PACT Booster Sessions
  - University of Michigan – Dr. Cheryl King & Team
- TBI Module for Assessment & Intervention
  - Denver VA – Dr. Lisa Brenner & Team
- Secure Data Management & Web-Based Programmed Forms
  - KAI Research, Inc.
- Blind & Independent Follow-Up Assessments
  - Duke University – Dr. David Goldston + COL Charles Engel's Expertise
  - 2 Seasoned Doctoral Level Psychologists at Duke as Study Assessors
- Statistical Support Team
  - KAI Research, Inc. + Replacement for Dr. Thomas Tenhave, UPenn

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## Final Products

- | ■ Dissemination Plan                        | ■ Study Deliverables   |
|---|--|
| ■ Peer-Reviewed Publications, Presentations | ■ Empirically Validated Inpatient Treatment + Follow-Up Care   |
| ■ DoD, VA, & Civilian Inpatient Facilities  | ■ Training Materials <ul style="list-style-type: none"><li>■ Providers &amp; Patients</li></ul>                      |
| ■ Adapt – Emergency Department Usage        | ■ PACT Treatment Guide <ul style="list-style-type: none"><li>■ TBI Module</li><li>■ Special Considerations</li></ul> |

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## QUESTIONS?

**Contact Information:**

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## **Appendix B**

### **Summary of Credentialing Communication with WRNMMC**

1. During the meeting, the credentialing procedures for psychology doctoral and master's level researchers who provide clinical services (e.g., assessment and/or psychotherapy) to patients hospitalized at the Walter Reed National Military Medical Center were discussed. It was agreed that all staff including the PI have some level of clinical research contact with patients at WRNMMC AND provide direct clinical services either at the time of the patient's inpatient psychiatric stay OR after his or her discharge via telephone contact.

2. The PI provided a brief history of credentialing experiences at the Walter Reed Army Medical Center, the National Naval Medical Center, and the new WRNMMC. The PI indicated that Dr. Michael West had previously assisted lab personnel with credentialing guidance and oversight. Personnel were never asked by the WRAMC Credentialing Committee or even allowed by the WRAMC Department of Clinical Investigations to document (in Essentris) contact with patients recruited into the clinical psychotherapy research studies. Once the BRAC transition took place, representatives from the lab (Drs. Dennis, Lunt, and Schendel) and the PI met with CAP Ralph and Mr. Fennewald on September 14, 2011. At that time, they were informed that given the WRNMMC policies, the team members would have to document their contact with the study patients in the Essentris records. However, during the meeting, it was discussed that the studies did NOT have IRB approval to do so and that it was needed to go back to the newly merged/formed WRNMMC IRB to request for a note entry into each participant's medical chart for EACH clinical study in the lab. It was also agreed that notes would be generic such that the studies would be able to obtain approval from the IRB and have a standardized set of procedures in place for documentation in the study participant's medical record. It is often customary to keep research and treatment records separate in order to provide maximum protection to the service member and/or dependent who agrees to participate in our study.

#### **Proposed Plan of Action - Requires Final Review and Approval for Implementation**

1. We currently have a total of 3 active studies (recruiting patients) at WRNMMC. We are awaiting approval to start with a 4th study. We have recently obtained approval from the WRNMMC IRB to insert standardized notes into the patients' medical record for one of our larger studies. Therefore, we will begin to do so. For two of our active studies (smaller studies), we will have to wait for approval but we can make sure that standardized documentation takes place once formal approval from the IRB has been obtained. For the 4th study, appropriate language has been inserted in the IRB application so that once we are ready to recruit, we can use the same outlined procedures. In summary, moving forward, for every patient who is recruited to participate in one of our psychotherapy research studies, we will insert an IRB approved entry into Essentris to simply document the enrollment and status of the patient in the context of research participation.

2. For the purposes of credentialing renewal and peer review of 8 records per quarter, the group agreed that it would NOT make sense to have these Essentris documented records reviewed given that all study personnel will be using the IRB approved Essentris template (Appendix J). Therefore, we discussed the possibility of having our research records be subject to peer review. These records are maintained at our laboratory space (Building 53) of the USUHS campus. We

discussed that each credentialed staff member in our lab can be designated to review the research records of a peer. The review will consist of the following: (a) review of correct delivery and documentation of psychological assessment; (b) review of correct delivery and documentation for psychotherapeutic intervention (for those patients randomized into the treatment condition); and (c) review of correct handling and documentation of risk management procedures. Once you formally approve this proposed plan of action, I can generate a list of peer review assignments and forward to you all for your records.

3. COL Dunivin indicated that we could either use the existing peer review form at WRNMMC OR develop a new one. COL Dunivin, WRNMMC to send a copy of the current peer review form so that our team can conduct a review and provide feedback about whether or not the form would be applicable/suitable for our purposes.

4. PI credentials renewal: There is currently not a full resolution for this matter. We agreed that since the PI's credentials have expired, that she must work under a plan of supervision and have a total of 8 records/quarter reviewed OR be considered for a research type of credentialing. COL Dunivin was going to think about who in the department of psychology can serve as a peer reviewer for the PIs records. The PI indicated that her primary responsibility at USUHS is research, teaching/mentoring, and providing individual as well as group supervision to study personnel. The PI rarely has contact with study participants because of limited time to be engaged in direct clinical activity. Most of the PI's efforts are focused on securing DoD grant funding for the conduct of clinical research at WRNMMC. For the purposes of maintaining credentials, the PI can begin to increase my direct patient services activities and document these for peer-review purposes OR simply begin to maintain supervision notes.

Having said all this, we continued to move forward and have now received initial approval of the project from the WRNMMC IRB. We will continue to problem solve challenges as they arise to ensure that our study objectives are met within a reasonable and timely manner.

### **Supporting Data**

There are no study findings and supporting data to report at the present time. We hope to begin recruitment in Year 3.